REMARKS

Applicants respectfully request the reexamination and reconsideration of the present application pursuant to 37 CFR § 1.112.

Claims 6 and 10 were rejected under 35 USC 103(a) as allegedly being obvious in view of SEIBERT et al. (U.S. Patent No. 5,872,986), JARADAT et al. (Biochemical Pharmacology 2001), and MESTRE at al. (Annals of the New York Academy of Sciences 1999). This rejection is respectfully traversed.

Applicants respectfully submit that the Official Action fails to satisfy its burden in showing that claims 6 and 10 were obvious in view of the above-identified publications. The Official Action fails to cite any page or line numbers in support of its positions. In this regard, applicants respectfully note that the Official Action is somewhat difficult to follow. Moreover, the Official Action could be considered improper as matter of law as the positions set forth in the Official Action stand as unsupported allegations. Nevertheless, in the interest of advancing prosecution, applicants have reviewed the Official Action and references cited therein and proceed as best as possible.

The claimed invention is directed to a method for screening selective inhibitors of COX-2 for therapeutic functionality (i.e., off-target effects) in addition to COX-2 protein inhibition (i.e., target effect). The method comprises testing a compound to determine whether the compound satisfies at least two of tests (a) – (g) as recited in claim 6. Compounds that satisfy the screening test are identified as compounds that may be useful for treating a patient having or at risk for cancer, Alzheimer's disease, or atherosclerosis.

None of the above-identified publications, alone or in combination, suggest screening for the off-target effects of selective COX-2 inhibitors, or using a plurality of tests as recited in claim 6.

SEIBERT relates to the use of selective COX-2 inhibitors for the prevention and treatment of neoplasia. SEIBERT teaches that the use of selective COX-2 inhibitors is "highly advantageous in that they minimize the gastric side effects that can occur with [non-selective nonsteroidal anti-inflammatory drugs] NSAIDs " (col. 3, lines 5-10).

SEIBERT neither discloses nor suggests screening for the off-target effects of selective COX-2 inhibitors. Moreover, there is no recognition that some COX-2 inhibitors may be more effective than others in light of their off-target effects.

In an effort to remedy the deficiencies of SEIBERT for reference purposes, the Official Action cites JARADAT.

JARADAT studies the effects of NSAIDs on the activation of peroxisome proliferator-activated receptor (PPAR) α and γ isoforms in CV-1 cells co-transfected with rat PPAR α and γ, and peroxisome proliferator response element (PPRE)-luciferase reporter gene plasmids for stimulation of peroxisomal fatty acyl CoA β-oxidase activity in H4IIEC3 cells, and for comparative inhibition of prostaglandin endoperoxide H synthase (PGHS)-1 and PGHS-2 and arachidonic acid-induced human platelet activation.

Applicants respectfully submit that JARADAT fails to remedy the deficiencies of SEIBERT for reference purposes.

In that SEIBERT leads one skilled in the art to use selective inhibitors of COX-2 and JARADAT focuses on the effects of NSAIDs, it is believed that one skilled in the art would lack the motivation to combine and modify the teachings of Seibert and JARADAT. Indeed, the chemical structure and function of selective COX-2 inhibitors are distinct from the chemical structure and function of NSAIDs. A selective inhibitor of COX-2 is a compound with a chemical structure that selectively inhibits COX-2 in preference to COX-1 (see published application, paragraph [0007]). However, NSAIDs have a very different structure that non-selectively inhibits both COX-1 and COX-2. Thus, selective COX-2 inhibitors and NSAIDS are distinct compounds with very different chemical structures and different functions.

Moreover, while JARADAT states that the effect of NSAIDs may be related to both inhibition of PGHS enzymes and to activation of PPAR, the word may does not provide one skilled in the art a reasonable expectation of success to combine and modify the publications in a manner that would result in a meaningful outcome.

In an effort to remedy the deficiencies of SEIBART and JARADAT for reference purposes, the Official Action cites to MESTRE.

MESTRE studies the inhibition of COX-2 as an approach to preventing head and neck cancers. In particular, MESTRE test for the suppression of EGFR mediated production of COX-2 with retinoids. However, MESTRE does not teach that selective COX-2 inhibitors exhibit this function. Moreover, such suppression is different from a decrease in the levels of or down regulation of expression of the compounds recited in the class 1 family of receptors

of tyrosine kinase of claim 6 (e.g., see step (b)). Thus, while the Official Action cites the second paragraph of page 69 of MESTRE in support of its position, applicants respectfully submit that this passage is irrelevant in light of the claimed invention.

Thus, it is believed that MESTRE fails to remedy the deficiencies of SEIBERT and JARADAT for reference purposes.

In imposing the rejection, the Official Action appears to believe that because overexpression of COX-2 has been associated with different cancers, it would have been obvious to look for different ways to determine COX-2 inhibition as discussed in the JARADAT and MESTRE publications (see Official Action, pg. 6, last full paragraph). However, applicants respectfully submit that this position does not take into consideration that the claimed invention is directed to a method for screening selective inhibitors of COX-2 for therapeutic functionality (i.e., off-target effects) in addition to COX-2 protein inhibition. Indeed, as noted above, none of the publications suggest specifically screening for the off-target effects of selective COX-2 inhibitors, or using a plurality of tests as recited in claim 6.

Thus, applicants respectfully ask that the rejection be withdrawn.

As the Examiner is aware, upon the allowance of a generic claim, an applicant is entitled to consideration of claims to additional species which depend from or otherwise require all the recitations of an allowable generic claim (see 37 CFR § 1.141). In that the proposed combination of SEIBERT et al., JARADAT et al., and MESTRE at al. fails to render obvious claim 6, which is generic to claims 7-9 and 11, applicants respectfully request that claims 7-9 and 11 should be rejoined at this time.

In view of the present amendment and foregoing remarks, therefore, applicants submit that the present application is in condition for allowance.

Respectfully submitted,

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